2017

BIOSECURITY PROGRAM ANNUAL REPORT

ADVANCING THE BIOSECURITY AGENDA PROMOTING

REGULATORY COMPLIANCE + SAFE SCIENCE IN CANADA

Public Health Agency of Canada
Agence de la santé publique du Canada

Canada

“To promote and **protect the health of canadians** through leadership, partnership, innovation and action in public health.”

—PUBLIC HEALTH AGENCY OF CANADA

Également disponible en français sous le titre :
Rapport annuel du programme de biosûreté 2017

To obtain additional information, please contact:
Public Health Agency of Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: hc.publications-publications.sc@canada.ca

Publication date: January 2020

Cat.: HP42-2E-PDF
ISSN: 2562-9689
Pub.: 190442

TABLE OF CONTENTS

The **Biosecurity Program** administers legislation and regulations designed to protect the health and safety of the public against the risks posed by human and terrestrial animal pathogens and biological toxins.

Pathogens and toxins pose a risk to the public because of their ability to cause disease or death.

The Biosecurity Program's various components are designed to prevent both the accidental release of these agents from a laboratory, including by way of an infected worker, and deliberate release by way of an act of terrorism or other criminal activity.

The Biosecurity Program also works with international counterparts to strengthen biosafety and biosecurity globally by building capacity and promoting uptake of best practices in other jurisdictions.

VISION

Biosafety as the foundation of Canadian innovation in life sciences.

MISSION

We deliver a strong and comprehensive safety and security regime that:

- Prevents, detects, and responds to the risks posed by the use of pathogens and toxins; and
- Fosters an enhanced national biosafety culture.

INTRODUCTION

Following a year of transition, the Biosecurity Program's 2017–2018 Annual Report illustrates how we executed our mandate, supported our regulated parties, and delivered a high caliber program for all Canadians through our strategic, evidence-based activities, compliance promotion materials, and coordinated global biosafety and biosecurity regulatory efforts.

Since December 1, 2015, the Biosecurity Program has been carrying out its mandate under the *Human Pathogens and Toxins Act* (HPTA) and the *Human Pathogens and Toxins Regulations* (HPTR). Our national approach encompasses a licensing regime that supports a strong culture of biosafety and biosecurity in Canadian laboratories, with the goal of reducing the risk of an accidental or deliberate release in the communities in which they are located.

The Biosecurity Program's risk-based regulatory framework maintains high standards for health and safety, while providing flexibility for industry to innovate and compete globally. With a strong orientation towards compliance promotion, the Program provides regulated parties with the guidance they need to understand why compliance is important and how to achieve it.

Focused on continuous improvement, we monitor and evaluate the impact of the regulatory framework. Compliance and enforcement data, as well as feedback from regulated parties and stakeholders, are used to identify gaps and develop better guidelines and tools, more targeted compliance and enforcement actions, as well as more efficient stakeholder outreach programs—all with the aim of helping organizations across the country improve their own biosafety and biosecurity practices. These informed, deliberate enhancements strengthen the Program and aim to reduce administrative and regulatory burden.

Through strong, strategic relationships, knowledge sharing, and active leadership, the Program endeavours to strengthen the biosafety and biosecurity culture across Canada, promote the safe use, and secure containment of pathogens and toxins globally.

This report summarizes 2017–2018 fiscal year data for the Biosecurity Program and marks our second full year under the HPTA and HPTR regulatory regime. With only two full years of operation, we are beginning to gain better insight into our regulated parties—their barriers to compliance and drivers to change—as well as the effectiveness of our oversight. As the Program matures, we will gain a more comprehensive understanding of both and leverage this knowledge to strengthen the Program and regulatory framework based on the best available evidence and science.

CANADA'S BIOSECURITY PROGRAM

Research and diagnostic work with pathogens and toxins are critical to public health, advancement of science, and innovation. This work also poses risks to public health and safety that must be addressed and managed at a national level.

The Public Health Agency of Canada's (PHAC) Biosecurity Program protects Canadians from risks associated with the use of pathogens and toxins by administering and enforcing *the Human Pathogens and Toxins Act* (HPTA),[1] the *Human Pathogens and Toxins Regulations* (HPTR),[2] as well as certain provisions of the *Health of Animals Regulations* (HAR)[3] related to the importation of terrestrial animal pathogens.

CORE PROGRAM ACTIVITIES

Our comprehensive, national approach to regulating pathogens and toxins includes:

- Licensing
- Security clearances for individuals accessing high-risk pathogens
- Pathogen risk assessments
- Incident and exposure reporting
- Standard and guidance development
- Stakeholder outreach and engagement
- Compliance monitoring, verification, and enforcement through inspections, audits, and document reviews

What is biosafety? The containment principles, technologies, and practices used to prevent unintentional exposure to or accidental release of pathogens and toxins.

What is biosecurity? The institutional and personal security measures used to prevent loss, theft, misuse, diversion, or intentional release of pathogens and toxins, and other related assets.

What is a pathogen? A microorganism capable of causing disease, ranging from common bacteria like Salmonella to viruses of significant public health concern like Ebola.

What is a biological toxin? A poisonous substance produced or derived from a microorganism. Biological toxins, like botulinum neurotoxin and cholera toxin, can cause adverse health effects in humans or animals.

---

1 HPTA: http://laws.justice.gc.ca/eng/acts/H-5.67/

2 HPTR: http://lois-laws.justice.gc.ca/eng/regulations/SOR-2015-44/index.html

3 HAR: http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._296/

HOW WE WORK

We are Canada's national authority for the biosafety and biosecurity of human and terrestrial animal pathogens and select biological toxins. Our highly skilled, professional staff are dedicated and committed to protecting the health and safety of the public against the risks posed by these agents.

We Set Requirements

Setting clear expectations

Requirements are established through legislation, regulations, and conditions of licence. The Program develops standards, pathogen risk assessments, directives, and advisories to address regulated party concerns and to provide current, comprehensive information to support regulated parties in fulfilling their responsibilities.

We Authorize Controlled Activities

Reviewing and assessing applications

Licence and security clearance applications are reviewed and assessed against regulatory requirements for the conduct of controlled activities, so that they may be undertaken safely and do not represent a risk to national security.

We Oversee and Enforce Compliance

Monitoring and verifying that the rules are being followed

Inspections and document reviews are conducted to monitor and verify compliance with applicable regulations, statutes (or Acts), conditions of licence, and a range of enforcement actions are used to address compliance issues. Biosafety and biosecurity risks are also identified and mitigated through laboratory incident notifications and border importation monitoring activities.

We Promote Compliance

Engaging with stakeholders, publishing guidance and reporting key information

Program staff engage with stakeholders through interactions and by publishing biosafety and biosecurity resources and tools to promote compliance and to protect the health and safety of Canadians.

Controlled activities: production, possession, handling, use, storage, access to, transfer, disposal, release, abandonment, import, or export of a regulated pathogen or toxin.

Pathogens are classified into **four Risk Groups** (RGs). The higher the risk, the more stringent the biosafety and biosecurity requirements:

	RISK GROUP 1	RISK GROUP 2	RISK GROUP 3	RISK GROUP 4
Individual Risk	Low	Moderate	High	High
Community Risk	Low	Low	Low	High
Examples	Brewer's yeast, *E. coli* K-12	Salmonella bacteria, Hepatitis A virus.	*Mycobacterium tuberculosis*, SARS virus	Ebola virus, Marburg virus

The HPTA applies to all persons and facilities in Canada that conduct controlled activities with **Risk Group 2, Risk Group 3, or Risk Group 4** human pathogens and toxins. Schedules 2 to 4 of the HPTA represent key examples of human pathogens regulated under the Act.

WHO WE REGULATE

Our regulated community is diverse and growing. Human pathogens and toxins are used by organizations in a wide range of sectors for many different purposes: teaching and research at universities, disease diagnosis at hospitals and public health facilities, vaccine development in the pharmaceutical industry, quality control in the food industry, and more.

As of March 31, 2018 a total of **979 licences** were distributed across the following sectors:

The Citizen Science / Do It Yourself community in Canada works with Risk Group 1 pathogens, which means they are outside the scope of the HPTA and do not require a licence. Regardless, we actively work with this unique and growing sector as part of our ongoing commitment to promoting biosafety and biosecurity awareness and fostering a culture of biosafety in Canada.

979 LICENSES

Industry	448	46%	**Gov. Environmental Health**	34	3%
Hospital	209	21%	**Gov. Public Health**	28	3%
Academic	201	21%	**Gov. Vet / Animal Health**	21	2%
Other Government	38	4%	**Citizen Science / Do It Yourself**	0	0

Pathogen and Toxin Licences

Conducting a controlled activity with a Risk Group 2 or higher human pathogen or a Schedule 1 toxin in Canada requires a **Pathogen and Toxin Licence,** with some exemptions and exclusions as defined in the *Human Pathogens and Toxins Act* and associated Regulations. The conditions of licence assigned to mitigate potential harm are based on the identified Risk Group level of the pathogen or list of prescribed toxins, as well as on the nature of the work being undertaken. These licences also serve as permits to authorize the importation and transfer of indigenous terrestrial animal pathogens regulated under the *Health of Animals Regulations* (HAR).

979 LICENSES

Risk Group 2	913	93%	**SSBA Toxin**	2	<1%
Risk Group 3	62	6%	**RSK Group 4**	2	<1%

HPTA Security Clearances

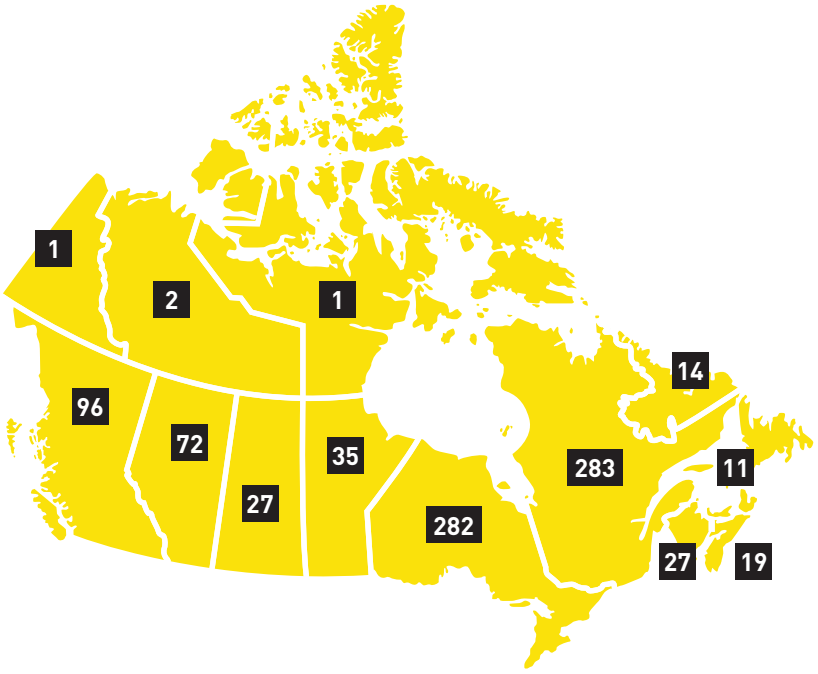
All individuals who work with or have access to a subset of Risk Group 3 and Risk Group 4 pathogens and select toxins known as Security Sensitive Biological Agents (SSBA) require an **HPTA security clearance.** These pathogens pose an increased biosecurity risk due to their potential for use as a biological weapon.

382 HPTA SECURITY CLEARANCES

Biological Safety Officers

A **Biological Safety Officer** (BSO) is the individual designated by a licence holder to oversee an organization's biosafety and biosecurity practices. They may be responsible for multiple licences.

870 BIOLOGICAL SAFETY OFFICERS ACROSS CANADA



OUR RISK-BASED APPROACH

We apply a risk-based approach to all licensing, compliance monitoring, verification, and enforcement activities. This means that as the risk of the activities involving pathogens and toxins increases, so do the requirements. Leveraging the best available evidence, knowledge, and science, our risk-based approach is used to:

- Determine the biosafety and biosecurity requirements for controlled activities conducted by regulated parties;
- Identify the frequency of ongoing compliance monitoring and verification activities;
- Prioritize our inspection activities; and
- Guide enforcement interventions so that actions taken are proportionate to the seriousness of the issue and are appropriate to the situation.

OUR OPERATING BUDGET

The Biosecurity Program's 2017–2018 operating budget totaled $9.2 million, with 71 full-time equivalent employees. These resources were allocated to support planned regulatory activities and cover the cost of operations.

RESPONSIBLE REGULATOR

We promote and enforce compliance with a broad set of regulatory requirements. Our regulatory oversight includes issuing licences and security clearances, conducting inspections and document reviews, surveillance of laboratory incident notifications, monitoring the import of regulated pathogens and toxins, and enforcing compliance when and where required.

We also use these interaction points to actively engage regulated parties in a collaborative dialogue and promote safe work with pathogens in laboratories across the country. Feedback obtained from these interactions, as well as the data collected, is essential for identifying program improvements.

Based on compliance monitoring, verification, and enforcement activities conducted throughout 2017–18, we have found that:

- Inspected laboratories are largely operating in compliance with the applicable legislative and regulatory requirements, and conditions of licence.
- All three laboratories found to be in major non-compliance upon inspection were brought into compliance within the established time frame for corrective actions; and
- Laboratory incidents resulting in confirmed or suspected infection or intoxication were low.

REGULATORY AUTHORIZATIONS

Licences

We issue **Pathogen and Toxin Licences** to organizations that conduct controlled activities with human pathogens and select biological toxins in Canada. These licences also serve as permits to authorize the importation and transfer of indigenous terrestrial animal pathogens regulated under the *Health of Animals Regulations* (HAR).

All **Pathogen and Toxin licences** require ongoing compliance with applicable requirements described in the Canadian Biosafety Standard (CBS) 2nd Ed., 2015.

The CBS is the harmonized national standard for handling and storing human and terrestrial animal pathogens and toxins in Canada.

In 2017–2018, the Biosecurity Program processed 307 licence applications.

SERVICE DELIVERY STANDARD	TARGET	RESULT
Issuance of Risk Group 2 Pathogen and Toxin Licences within **80 business days** from receipt of a completed application. This applies only to applications that do not require additional information.	80%	100%

We surpassed our established service standard for the issuance of a Risk Group 2 Pathogen and Toxin Licence with 100% issued within 80 days. The average issuance took just 17 business days, with our shortest and longest issuance times ranging from 1 to 71 days respectively. The vast majority of applications were for variations (i.e. amendments) to existing licences.

HPTA Security Clearances

To mitigate biosecurity risks all individuals with access to Security Sensitive Biological Agents (SSBA) require a valid HPTA security clearance. We work in collaboration with other federal partners, including the Canadian Security Intelligence Service and the Royal Canadian Mounted Police to assess the personnel reliability of all applicants through the HPTA security clearance process.

In 2017–2018, the Biosecurity Program processed 29 security clearance applications.

SERVICE DELIVERY STANDARD	TARGET	RESULT
Acknowledge receipt of an application within 5 business days from receipt of an HPTA security clearance application.	80%	21%
Issuance of HPTA security clearances within 80 business days from receipt of a completed application. This applies only to applications that do not contain adverse information.	80%	45%

While we **did not meet our service standards** for HPTA security clearances, we are monitoring this service area closely and working to address identified administrative challenges both in the short-term through procedural fixes and in the longer-term through information technology solutions.

COMPLIANCE MONITORING, VERIFICATION, AND ENFORCEMENT

Compliance is assessed through laboratory inspections and document reviews. Monitoring of pathogen imports at the border and surveillance of laboratory incident notifications are also key components of our monitoring activities.

If we determine an organization has not met a requirement directly prescribed by legislation or a condition of their licence as required under HPTA 18(4), corrective actions are required to bring it into compliance. Enforcement actions are typically undertaken in a progressive manner—our primary objective is to manage risk and compel the regulated party into compliance using the most appropriate level of intervention.

Inspections

All licences come with conditions related to biosafety and biosecurity that must be met by every person conducting controlled activities under that licence.

The Program uses risk-based criteria to select Risk Group 2 sites and to prioritize Risk Group 3 sites for inspection, as per the Policy on Compliance Monitoring, Verification, and Regulatory Risk-Based Activities.

In 2017–2018, the Biosecurity Program inspected 73 licences.

PHAC's Regulatory Compliance & Enforcement Framework sets out the Agency's general approach and philosophy to compliance and enforcement, and articulates the key activities carried out by its regulatory programs to verify and compel regulated parties into compliance.

Inspection Targets

We inspect a percentage of Risk Group 2 licences every year selected from risk-based criteria. We inspect Risk Group 3 and Security Sensitive Biological Agent Toxin licences once during the term of their licence (typically three years), and Risk Group 4 licences every year. Targets are based on the number of active licences as of March 31, 2017.

RISK GROUP 2	RISK GROUP 3	RISK GROUP 4
Target: 2% of 885 RG2 Licences = 18	**Target:** 33% of 61 RG3 Licences = 20	**Target:** 100% of RG4 Licences = 2
Result: 45 (5%)	**Result:** 28 (46%)	**Result:** 2 or (100%)

We **surpassed our annual inspection targets for 2017–2018** by creating efficiencies in our inspection approach and optimizing inspection resources. These efficiencies were gained through internal reorganization and investments in cross training of inspectors and through our inclusion of geographically proximate Risk Group 2 inspection sites during planned Risk Group 3 licence inspection travel. Our inspectors are now trained to inspect all types of facilities, which has led to an increase in the availability of qualified inspectors.

Inspection Findings

Inspectors verify compliance of regulated facilities under the legislative authority of the HPTA, HPTR, HAA and HAR and applicable requirements of the Canadian Biosafety Standard, 2nd Ed. In keeping with our commitment to compliance promotion, inspectors engage with a facility's BSO through open channels of communication. Throughout the inspection process, inspectors ensure that findings are addressed and communicated to the BSO on-site during the inspection and in an inspection report.

In 2017–2018, upon inspection the Biosecurity Program identified 481 deficiencies with Canadian Biosafety Standard requirements and 14 non-compliances with HPTA and HPTR requirements.

TOP 3 CANADIAN BIOSAFETY STANDARD (CBS) 2ND ED. CATEGORIES REQUIRING CORRECTIVE ACTION IN 2017–2018

Risk Group 2	Risk Group 3
4.1 Biosafety program management	**4.10 Records and documentation**
46 inspection sites required corrective actions related to CBS requirements in Section 4.1. Most deficiencies in this category were related to institutional biosafety programs not carrying out regular assessments of training needs. This is a result of the implementation of more stringent training program requirements with respect to identifying training needs and refresher training for those working in laboratories.	22 inspection sites required corrective actions related to CBS requirements in Section 4.10. More than half (55%) of the deficiencies in this category were related to pathogen and toxin inventory. For example, the location or risk group of pathogens had not been recorded, both of which are new requirements under CBS 2nd ed.

TOP 3 CANADIAN BIOSAFETY STANDARD (CBS) 2ND ED. CATEGORIES REQUIRING CORRECTIVE ACTION IN 2017–2018

Risk Group 2	Risk Group 3
4.3 Training	**4.6 Work practices**
45 inspection sites required corrective actions related to CBS requirements in Section 4.3. Of those, approximately 38% were due to facilities not conducting refresher training on the emergency response plan at least annually; this requirement was newly introduced in the CBS 2nd edition.	19 inspection sites required corrective actions related to CBS requirements in Section 4.6. Nearly half (47%) of the deficiencies were related to the use of primary containment devices (e.g. biological safety cabinets, isolators, centrifuges with sealable cups, ventilated caged racks, etc.), in which most open-vessel work with Risk Group 3 human pathogens takes place.
3.4 Surface finishes and casework	**3.4 Surface finishes and casework**
42 inspection sites required corrective actions related to CBS requirements in Section 3.4. The majority (83%) of deficiencies in this category were related to surfaces and materials requiring replacement, removal, or repair. These deficiencies are historically the most commonly seen in containment laboratories as they experience the usual wear-and-tear and frequent use of harsh disinfectants.	19 inspection sites required corrective actions related to CBS requirements in Section 3.4. Surface deficiencies requiring corrective action were observed under Risk Group 3 licences at a comparatively lower rate (63%) than observed for Risk Group 2. Requirements for maintenance practices and surfaces to be more robust at CL3 are likely contributing factors to this trend.

TOP NON-COMPLIANCE UNDER THE HPTA AND HPTR IN 2017–18

Over 33% of non-compliances related to licensing components of the HPTA (Sections 18, 36). This result is not surprising given the recent implementation of the licensing regime and the learning curve required of regulated parties to understand the conditions and obligations associated with their licences. An example of a common non-compliance with the HPTA (Section 36(6)) is when an individual ceases to act as the BSO and the licence holder fails to designate a replacement and inform PHAC without delay.

Trends and Future Action

In 2017–18, the majority of licensed organizations were entering the second year of their licence term(s). With only a single year of inspection data under the new licensing regime, the depth of data is insufficient to fully identify trends. Once sufficient data is collected to allow comprehensive analysis, the Program can better determine where compliance promotion can be developed or improved in an effort to increase laboratory compliance. Additionally, the risk-based inspection selection criteria will undergo regular evaluation and improvement based on information and evidence gleaned from ongoing inspections. Though limited, the analysis of the common inspection findings requiring corrective actions informed the development of outreach activities discussed later in this report, including a webinar, newsletter articles and workshops.

Documentation Reviews

Conducted remotely, document reviews are used to enhance compliance monitoring and verification interventions. Applying our risk-based approach, in 2017–2018, we prioritized the review of two specific plans—the Plan for Administrative Oversight (PAO) and the Biosecurity Plan—and piloted a broader compliance document review process. These concerted efforts facilitated compliance across areas of higher risk and provided an opportunity to engage regulated parties and promote safe work with pathogens in laboratories across Canada.

Plan for Administrative Oversight (PAO) of Pathogens and Toxins in a Research Setting

The PAO is a **new regulatory requirement** designed to mitigate risks unique to the research sector. When applying for a licence, facilities that conduct scientific research must submit a PAO setting out how biosafety and biosecurity risks will be administratively managed.

In 2017–2018, the Biosecurity Program completed 139 PAO reviews.

EXPECTED RESULT	PERFORMANCE INDICATOR	TARGET	RESULT
Licensed facilities conducting scientific research have effective controls, governance and risk management processes in place.	Percentage of assessed PAOs with a compliant rating.	95% (by March 2020)	40%

We are on-track to achieve our 2020 PAO target, having accomplished a significant improvement from just 2% in 2016–2017. Based on the feedback provided in the PAO Evaluation Report, licensed facilities continue to make improvements to their PAOs. Approximately 65% of PAOs reach compliance after the second review and we anticipate that nearly all PAOs will reach compliance by the third review.

Biosecurity Plans

All facilities require a biosecurity plan outlining the security measures in place to prevent the loss, theft, misuse, diversion, or intentional release of biological assets and related facility assets. Representing the highest risk, facilities that work with Security Sensitive Biological Agents (SSBAs) must submit their existing Biosecurity Plan with their licence application.

In 2017–2018, the Biosecurity Program completed a total of 23 SSBA-related Biosecurity Plan reviews.

EXPECTED RESULT	PERFORMANCE INDICATOR	TARGET	RESULT
Facilities licensed to work with SSBAs have effective security measures in place.	Percentage of assessed SSBA-related biosecurity plans with a compliant rating.	90% (by March 2019)	82%

We are **on-track to achieve our Biosecurity Plan target** with 82% of SSBA-related Biosecurity Plans having reached compliance. This marks a major improvement from 2016–2017, where none of the plans had reached an acceptable level of compliance. These significant gains in compliance can be attributed to the publication of the Canadian Biosafety Guideline on Developing a Comprehensive Biosecurity Plan (June 2016) and feedback provided in the Biosecurity Plan Evaluation Report. We anticipate that all SSBA-related Biosecurity Plans will reach compliance by March 2019.

Compliance Documentation Review Pilot

A document review pilot was initiated in the third quarter of the fiscal year, which focused on establishing first contact with regulated parties that had little to no previous compliance history.

HIGHLIGHTS	
Who:	Ten Risk Group 2 licensed facilities that had limited or no previous compliance history with the Biosecurity Program were randomly selected. One additional unplanned document review of a Risk Group 2 facility was added to the pilot.
What:	Using evidence-based criteria, documentation pertaining to pathogen inventory, primary containment, and decontamination and waste management was requested.
How:	Selected regulated parties were notified electronically and given one month to submit all requested information.
Results:	100% of requested documents were submitted on time—demonstrating the effectiveness of our communication and the willingness of regulated parties to comply. The pilot project allowed our document review team to establish awareness of the Program and promote biosafety and biosecurity.
Next Steps:	Evaluation reports are in the process of being issued, as well as clarifications and follow-ups with the regulated parties. Completed data analysis for the pilot project will be available in the 2018–2019 fiscal year and will be used to inform Phase 2 of the pilot.

Enforcement and Overall Gains in Compliance

The Biosecurity Program tracks and reports on how licensed laboratories respond to direction to mitigate risks by implementing required corrective actions identified through the program's compliance monitoring and verification activities. Corrective actions and their associated implementation timelines are logged and tracked in a central repository. Our inspectors engage with BSOs to ensure they are implemented within established timelines. Failure to implement required corrective actions within established timelines results in additional enforcement measures.

EXPECTED RESULT	PERFORMANCE INDICATOR	TARGET	RESULT
Regulated organizations comply with legal and regulatory requirements and improve biosafety and biosecurity at their facilities.	Percentage of compliance issues in Canadian laboratories successfully responded to within established timelines.	85%	82%

Although the **target was missed by 3%,** the majority of the corrective actions that were not successfully responded to on time were completed within ten days past the due date. Further analysis of the results will be completed to better understand barriers to timely compliance and to inform program improvements.

MONITORING PATHOGENS AND TOXINS AT THE BORDER

All individuals and facilities that import pathogens and toxins into Canada require appropriate authorization to do so. With data provided to us by the Canada Border Services Agency (CBSA), we identify pathogen and toxin imports that require formal review and conduct appropriate regulatory action.

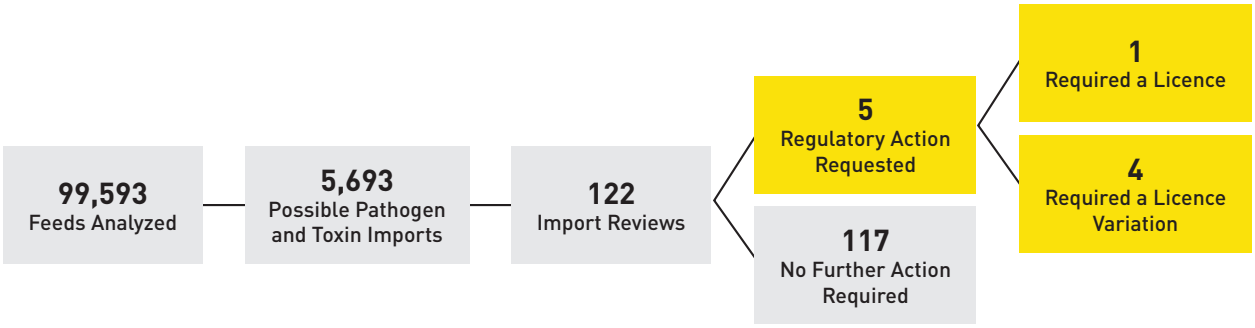
The data we receive from the CBSA has resulted in the identification of facilities previously unknown to us who may be conducting controlled activities with regulated pathogens and toxins. We continue to collaborate with the CBSA to enhance monitoring at the border through the Single Window Initiative.

The CBSA's **Single Window Initiative** facilitates efficient border processing by offering importers and brokers a unified pre-clearance solution for regulated commercial imports—including pathogens and toxins. pathogens and toxins in Canada.

Border Importation Monitoring Findings

We analyze close to 100,000 feeds of importation data annually, broadly filtered by CBSA, to identify potential illegal pathogen and toxin imports that require formal review and may result in regulatory action if found non-compliant.

In 2017–2018, the Biosecurity Program completed 122 import reviews.



LABORATORY INCIDENT REPORTING

Reporting exposures and non-exposure incidents involving regulated human pathogens and toxins is mandatory for all licensed facilities across Canada. These laboratory incident notifications are monitored through the Laboratory Incident Notification Canada surveillance system.

The data collected informs evidence-based decision-making regarding biosafety and biosecurity and facilitates early response—to prevent and mitigate biosafety risks and strengthen biosafety and biosecurity standards and guidelines. Mandatory reporting also facilitates near real-time detection of trends and potential patterns of concern in laboratory incidents, which we use to identify risk factors and address emerging public health and safety risks.

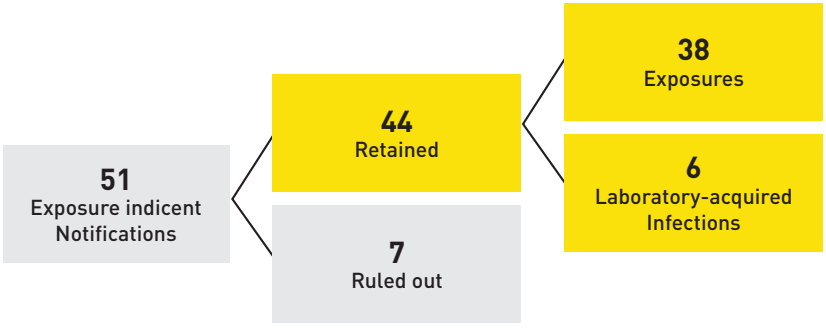
Since the launch of Laboratory Incident Notification Canada surveillance system in December 2015, **incident notifications reported through the surveillance system have steadily increased**. This supports our hypothesis that reporting will continue to increase for a number of years before reaching a steady state. The observed trend is consistent with program expectations—as regulated parties become more aware of and habituated to reporting requirements, the reporting frequency will continue to increase over the next few years.

Each year, the Biosafety Program publishes in the Canada Communicable Disease Report (CCDR), a **detailed report** on the surveillance of laboratory exposures to human pathogens and toxins in Canada.

Exposure-related incidents

Any contact with, or close proximity to, human pathogens or toxins that may result in laboratory-acquired infections or intoxication is considered an exposure and must be reported through the Laboratory Incident Notification Canada surveillance system.

In 2017–2018, the Biosecurity Program received 51 exposure incident notifications.

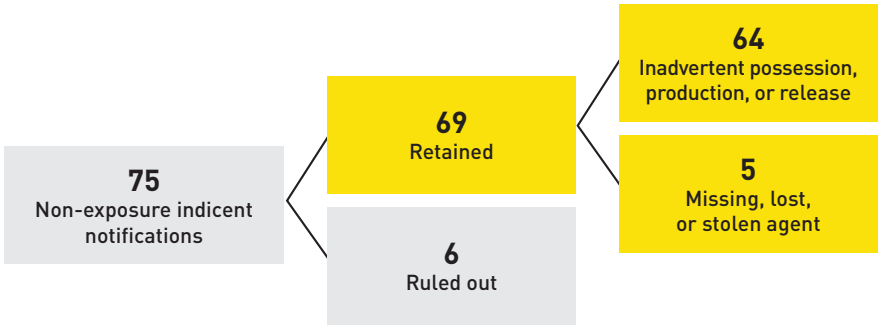


Overall, the incidence of **laboratory exposures to pathogens and toxins remained relatively low**, with a total of 44 retained incidents representing less than 5% of all licensed facilities. Most reports were related to inadequate procedures, breaches in procedures, and handling of sharps. Accordingly, standard operating procedures and human error were cited most frequently as root causes of these incidents.

Non-exposure related incidents

Any inadvertent possession, production, or release of a human pathogen or toxin, any missing, lost or stolen biological agents, or an SSBA not received within 24 hours of expected arrival must also be reported to the Program.

In 2017–2018, the Biosecurity Program received 75 non-exposure incident notifications.



Overall, **non-exposure laboratory incidents remained relatively low**, with a total of 69 retained incidents nationwide. Most reports were related to inadvertent possession, production, or release—often from routine diagnostic activities that resulted in unintended production of higher-risk pathogens. Very few involved missing, lost, or stolen biological agents and of those, the vast majority were due to inventory discrepancies, with only a single incident involving an inventory discrepancy with an SSBA.

PROMOTING COMPLIANCE

Evidence shows that compliance is higher when regulated parties understand why it matters and how to achieve it. We conduct outreach and engagement activities to build awareness and promote a deeper understanding of biosafety and biosecurity among our stakeholders and an informed and knowledgeable regulated community.

The Program aims to provide regulated parties and stakeholders with a range of guidance, resources, and tools to support them in identifying and mitigating biosafety and biosecurity risks and fulfilling their obligations under the HPTA and HPTR. Our outreach and engagement efforts are informed by sector-based intelligence and stakeholder feedback (e.g., from inspections, document reviews, incident reports, regional intelligence, correspondence, and surveys).

Stakeholder engagement activities and resources include guidelines, training, webinars, engagement at conferences, e-blasts, and newsletters. They are prioritized to address identified gaps and needs to better promote compliance with the regulatory framework. These tools are also used to inform stakeholders of important program and regulatory developments.

MANAGING THE REGULATORY FRAMEWORK

In light of new scientific knowledge and to maintain the integrity of the human pathogens and toxins regulatory regime, we reviewed the Schedules of the HPTA in consultation with the external Advisory Committee on Human Pathogens and Toxins.

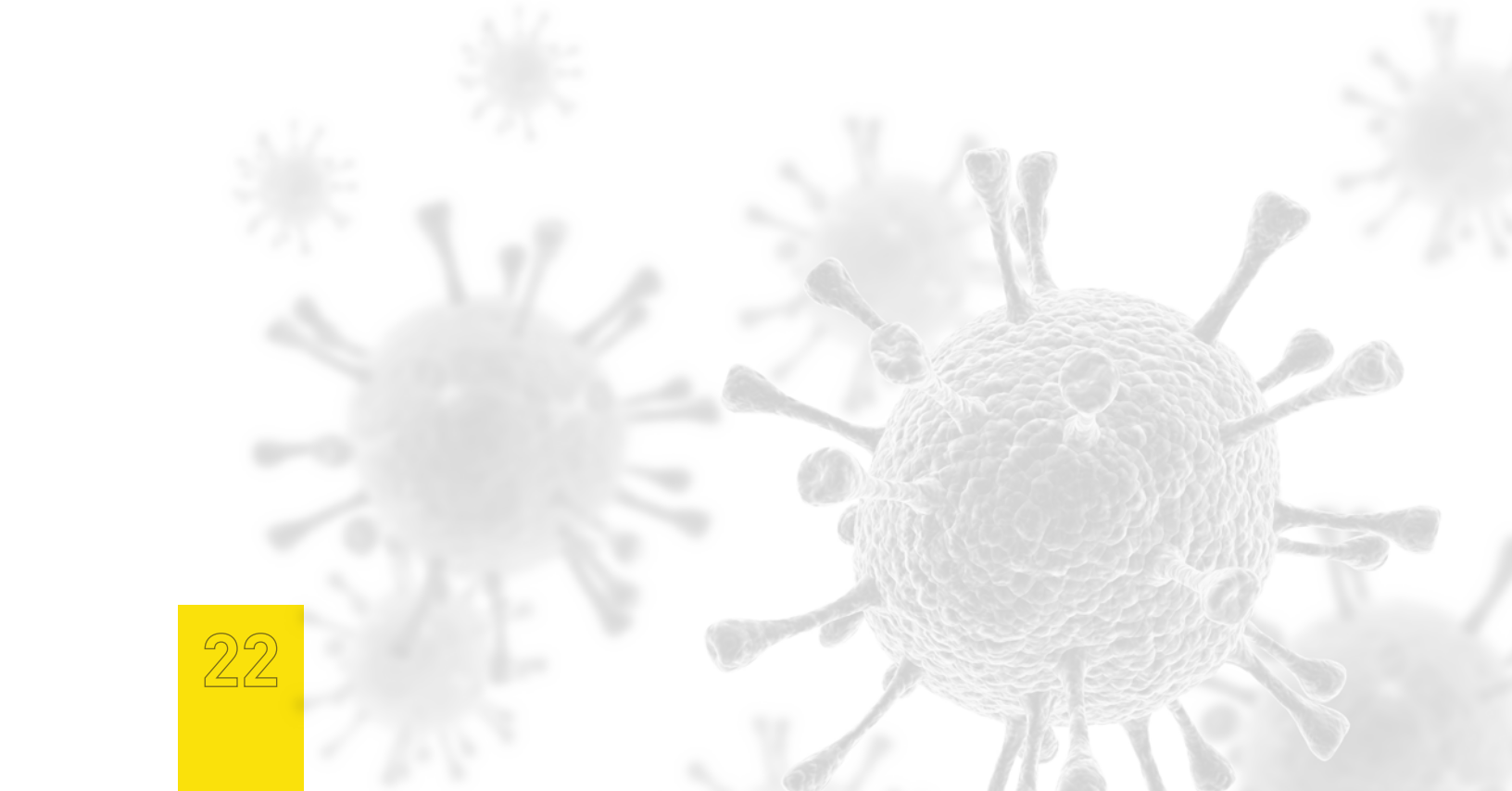
A foundational reference point for risk group classifications for all stakeholders, Schedules 2 to 4 of the HPTA represent key examples of human pathogens regulated under the Act. Over the summer of 2017, evidence-based changes to these schedules were proposed through public consultation and all feedback was taken into consideration. The final amendment to the Schedules was published in the Canada Gazette, Part II, on December 27, 2017.

As part of our commitment to enhancing the transparency and efficiency of our regulatory authorization and compliance processes for regulated parties and stakeholders, the regulatory framework was enhanced in 2017 with the publication of two foundational documents:

PUBLIC HEALTH AGENCY OF CANADA REGULATORY COMPLIANCE AND ENFORCEMENT (C&E) FRAMEWORK	POLICY ON COMPLIANCE MONITORING, VERIFICATION, AND REGULATORY RISK-BASED ACTIVITIES
This framework articulates the key activities carried out by the Agency's regulatory programs to verify and compel compliance. It helps to set expectations and demonstrates that there is a fair, consistent, transparent, and predictable approach to compliance and enforcement.	This policy clarifies the risk-based criteria considered when deciding on the most appropriate way to monitor and verify compliance and conduct enforcement activities. It is used to guide decisions on licence terms and conditions, selection of inspection sites, and assessments regarding a regulated party's compliance level.

Canadian Biosafety Guidelines

Our guidelines describe best practices for meeting requirements specified in the Canadian Biosafety Standard 2nd Ed., and expand on the biosafety and biosecurity concepts in the Canadian Biosafety Handbook (CBH). They also provide additional guidance for targeted audiences, such as teaching laboratories and diagnostic clinics.



In 2017–2018, we published five new Canadian Biosafety Guidelines:

VETERINARY PRACTICES: PHYSICAL DESIGN AND OPERATIONAL PRACTICES FOR DIAGNOSTIC ACTIVITIES	CONTAINMENT LEVEL 1: PHYSICAL DESIGN AND OPERATIONAL PRACTICES
Provides risk-based biosafety precautions and additional recommendations for veterinary facilities performing laboratory analyses and diagnostic testing with Risk Group 2 human pathogens.	Provides risk-based biosafety practices for facilities handling Risk Group 1 biological material. It also serves as the foundation for all of the biosafety requirements outlined in the CBS.
LOCAL RISK ASSESSMENT	**NOTIFICATION AND REPORTING UNDER THE HTPA AND HPTR**
Describes best practices for conducting a local risk assessment in an organization where human or animal pathogens, toxins, or other regulated infectious material are handled or stored.	Describes how to complete and submit incident notification reports and, where exposure or laboratory acquired infections/intoxications are concerned, subsequent follow-up reports to the PHAC.
CONDUCTING A BIOSECURITY RISK ASSESSMENT	
Describes best practices for conducting a biosecurity risk assessment in an organization where human or terrestrial animal pathogens, toxins, or other regulated infectious material are handled or stored.	

Through targeted outreach and engagement with the **Canadian Veterinary Medical Association (CVMA)**, the Program identified veterinary facilities that may have been doing work that would be captured under the scope of the HPTA. To address this potential oversight and promote compliance among this newly regulated sector, a guideline was developed specific to veterinary institutions that fall within the scope of the HPTA and an article about the HPTA/HPTR was published in the CVMA's Canadian Veterinary Journal.

Directives and Advisories

Biosafety Directives provide regulated parties with customized containment requirements for activities involving a specific pathogen or group of pathogens, when the containment level does not align with the risk group. **Biosafety Advisories** are developed when data obtained from a risk assessment of a new or emerging pathogen of interest indicates that new physical or operational requirements are required to work with the pathogen safely. New operational and physical requirements need to be disseminated to interested parties as soon as possible.

In 2017—2018, the biosafety directive for human immunodeficiency virus (HIV), human T-lymphotropic virus (HTLV), and related simian retroviruses was updated. It advised regulated parties that these Risk Group 3 pathogens, can be safely handled at a lowered containment level (CL2/CL2-Ag) with specific additional operational requirements.

Pathogen Safety Data Sheets

Our Pathogen Safety Data Sheets (PSDSs) are technical documents that give organizations across Canada—and around the world—instant access to information on the hazards of various pathogens and how to work with them safely in a laboratory setting.

PSDS web content is one of the Public Health Agency of Canada's most widely accessed pages. For 2017–18:

Top 5 countries accessing PSDS:

- Canada
- France
- United States
- Belgium
- Algeria

189
PSDSs online

540k +
page views

Although the online PSDS documents are in high demand, not all agents are covered. **In 2017, we published a** Pathogen Safety Data Sheet Template that can be used by an individual or organization to create a PSDS that complies with Canadian standards. The fully editable template comes with guidance and allows an individual/organization to use their own referencing software.

TAILORED RESOURCES AND TOOLS

We strive to continuously improve the way our stakeholders and regulated parties are informed and engaged—adopting digital best practices and exploring new technologies to better meet the needs of our community. As part of this, we are focused on the delivery of digital information, improved access to online content, and modernized online tools that are more effective.

Mobile Applications

We currently offer two mobile applications that are free to download for Android, Apple, and Windows devices. These apps are updated regularly and provide relevant biosafety information.

Canadian Biosafety Standard App

The Canadian Biosafety Standard (CBS) App lets users filter the current CBS requirements based on their facility (i.e. small animal work area in a containment level 2) and create dynamic checklists that can be used as part of a self-verification system for facilities to strengthen internal accountability systems.

6,077

CBS app downloads since launched in November 2014

In 2017–2018, we updated the app based on user and stakeholder feedback with:

- **New content:** All published Canadian Biosafety Guidelines.
- **Enhanced features:** Including pop-up definitions, collapsible matrices, search functionality, and the option to save or email custom lists.

Pathogen Safety Data Sheet App

The PSDS App lets users view any published PSDS from the convenience of their mobile devices.

20,820

PSDS App downloads since launched in April 2015

Online Courses and e-Learning

Through our Laboratory Biosafety and Biosecurity e-Learning Portal, we offer free online training and resources on laboratory biosafety. All of our online resources are developed and updated to address needs and knowledge gaps identified through regulatory activities and data analysis, as well as through feedback received from our regulated parties.

The portal features more than 24 courses and videos on a wide range of topics, including general introductions to biosafety and biosecurity, an overview of microbiology, pathogen and toxin risk assessments, information on laboratory-acquired infections and biomedical waste management, walk through videos of containment labs, and more. The online courses provided can be used by BSOs as a compliment to their employee training programs and allows for tracking employee training progress, thereby supporting their role as a BSO.

15,425

Courses complete by portal users—up 40% from 2016–17

In 2017–2018, the Biosecurity Program developed 3 new courses and updated 7 existing courses on the e-Learning Portal.

INTRODUCTION TO DUAL-USE IN LIFE SCIENCE RESEARCH

Developed to increase awareness on dual-use and to promote the responsible conduct of research. The generalized lack of understanding regarding the concept of dual-use and the potential reluctance of researchers to identify work with dual-use potential due to fear of repercussions on their work was noted by the Advisory Committee on Human Pathogens and Toxins in 2018 where it was suggested that additional training material and tools would be beneficial to address these issues.

WHAT TO EXPECT WHEN YOU'RE INSPECTED

Designed to promote compliance and enhance transparency, this course primes regulated parties on how to prepare for an inspection, what to expect during the visit, and how to address any corrective actions.

INTERACTIVE BIOCONTAINMENT TOOL

An interactive game developed to raise awareness of biocontainment in high schools and universities. It serves as outreach for the next generation of scientists in Canada.

UPDATES TO EXISTING COURSES

- Small Animals in Containment
- Large Animals in Containment
- Microbiology Overview
- Decontamination in the Laboratory
- Chemical Disinfectants
- Decontamination Technologies
- Biomedical Waste

Biosafety Webinar Series

In 2017, we launched a new biosafety webinar series aimed at engaging BSO networks and the broader biosafety community. The webinar series provides an opportunity for regulated parties and other stakeholders to ask questions and interact with our staff on specific topics.

Topics are selected based on the needs of our stakeholders as identified through our compliance monitoring activities and using feedback surveys from previous webinars.

The new series has garnered high participation and satisfaction rates among participants.

The first webinar—What to Expect When You're Inspected—was held in March 2018. A total of 440 participants (22% French and 78% English) attended and reported an 85.7% satisfaction rate.

Biosecurity Portal

The Biosecurity Portal allows regulated parties to securely exchange information with the Biosecurity Program and access the biological agent search function. It streamlines licence application, amendment, and renewal processes and provides a centralized location for regulated parties to create, store, and submit mandatory reporting activities.

The Portal serves as the Program's fully integrated, shared case management system and maintains a comprehensive compliance history for all licensed facilities. **Our 2017–2018 updates and enhancements resulted in:**

- Greater cross-functional collaboration for internal processes;
- Improved delivery time and automation for external reports; and
- Stronger security roles and processes to further reduce risks following results of a security audit.

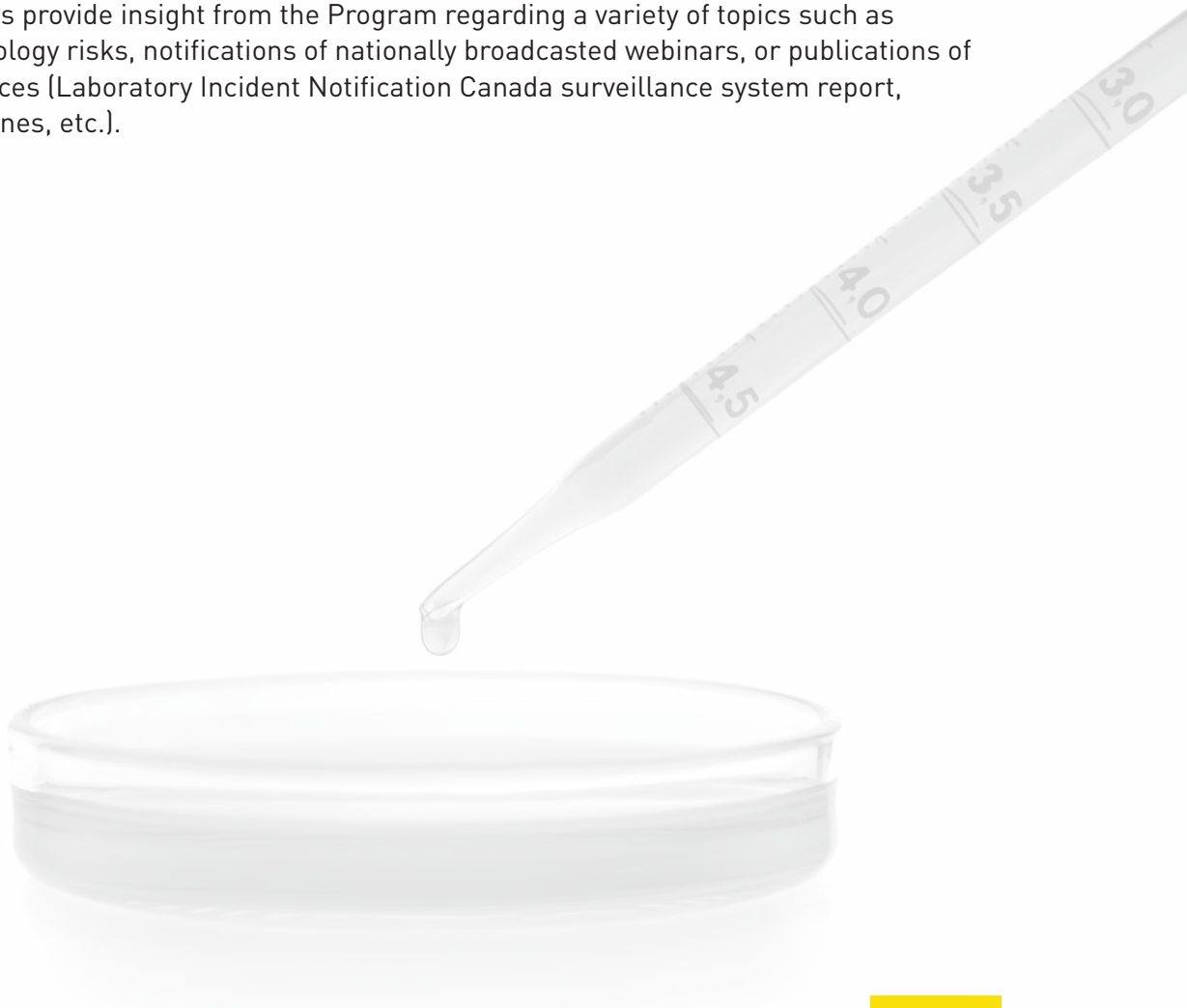
STAKEHOLDER COMMUNICATION

Biosecurity Program Newsletter

Our subscription-based newsletter is distributed quarterly, and provides information on an array of topics, including evolving issues, new tools or available resources. The newsletter is available to all regulated parties and members of the biosecurity and biosafety community and acts as an additional biosafety resource fostering the development of biosafety programs and culture

e-Blasts and Email

When appropriate, we use e-blasts or direct email to rapidly disseminate critical, time sensitive, and/or targeted information. The e-Blasts are typically targeted to either specific sector or group of recipients such as all Licence Holders and/or Biological Safety Officers. These quick, official messages provide insight from the Program regarding a variety of topics such as emerging technology risks, notifications of nationally broadcasted webinars, or publications of biosafety resources (Laboratory Incident Notification Canada surveillance system report, biosafety guidelines, etc.).



INFLUENCING BIOSAFETY IN CANADA

The HPTA regulatory regime supports a strong culture of biosafety and biosecurity in laboratories across Canada. We now have a clearer picture of who is working with pathogens and toxins and confidence that organizations with laboratory facilities are following appropriate standards to safely use and securely contain them.

While we strive to lead and strategically influence safe and responsible science—the success of our work is contingent upon our regulated parties and broader stakeholder community actively engaging, promoting, and contributing to the continued development of a strong biosafety culture across Canada, both within and outside of traditional settings.

To further promote a more collaborative approach to biosafety and biosecurity, we actively engage with Government of Canada colleagues to identify pathogen oversight gaps and potential areas of overlap. This work also serves to reduce administrative efforts and resources and to build strong relationships.

GRASSROOTS INITIATIVES

Each licensed facility or organization has a designated BSO responsible for overseeing the organization's biosafety and biosecurity practices. These officers hold an important role in upholding the facility's obligations under the HPTA and serve as our primary point of contact. This promotes greater institutional accountability and best practices throughout their operations.

BSOs also play a vital role in shaping biosafety culture both at the institutional level and nationally. Sharing best practices, resources, and tools, BSOs are working together to establish and strengthen networks. The Canadian Academic Biological Safety Officer's Network being led out of the University of Alberta, the Atlantic Region Network led by the BSO for the Provincial Public Health Laboratory Network of Nova Scotia and the Canadian Public Health Laboratories Network—Biological Safety Officers Network are such examples. The objective of these networks is to promote a forum for exchanging information and ideas between BSOs from research and diagnostic facilities across Canada.

DO IT YOURSELF BIOLOGY

Significant advancements in life science research are transforming the way biological experiments are conducted. We recognize the potential benefits of emerging technologies and encourage individuals to take an active interest in scientific innovation in a safe and responsible manner.

A growing global movement, "Do it yourself" (DIY) biology and citizen science involves scientists, engineers, students, and hobbyists who pursue biology outside traditional laboratory settings. Many members of the DIY biology community also support local schools and mentor students preparing for competitions. In this way, the DIY biology community plays a role in shaping future scientists.

As part of our ongoing commitment to creating a culture of biosafety in Canada and promoting biosafety and biosecurity awareness, we actively work with this unique sector to support scientific innovation and encourage scientific freedom. In 2017–2018, we attended the Canadian Synthetic Biology conference and engaged the DIY and citizen science research community.

NEXT GENERATION OF SCIENTISTS

As technology advances, people at younger ages are working with pathogens. Engaging the next generation of scientists involves reaching out to cohorts of students through various events, science fairs, and competitions to raise awareness of biosafety and biosecurity at the elementary and high school levels.

To orient students to containment labs, we developed three new biosafety and biosecurity posters for classroom labs and a series of educational videos in 2017–2018.

WHAT IS BIOSAFETY?	WHAT IS BIOSECURITY?
This poster introduces classroom laboratories to biosafety and working with biohazards.	This poster introduces classroom laboratories to the basic concepts of biosecurity.
BIOSAFETY IN ACTION	**WALKTHROUGH VIDEOS OF CONTAINMENT LABS**
This poster provides classroom laboratories with information on how exposures to biohazards can occur and how to protect oneself and others when using biohazards.	This video series provides students with the ability to virtually walk through examples of CL2, CL3, and CL4 laboratories

Canada-Wide Science Fair (CWSF)

Bringing science, technology, engineering, and math (STEM) out of the classroom—the CWSF engages youth in STEM solutions for real life issues. Hosted by the University of Regina, the 2017 CWSF had 26 exhibiting organizations, over 500 student finalists, 300 judges, and 10,000 visitors.

In addition to promoting biosafety, attending the CWSF also provides insights into the types of projects and activities being conducted across the country. To enhance engagement with students, teachers, and instructors, and strengthen their biosafety knowledge, we joined the CWSF Safety and Ethics committee in January 2018.

At the **CWSF**, we connected with the following key exhibiting organizations that can assist us in our efforts to develop appropriate resources and reinforce biosafety: The University of Regina; Carleton University; the National Research Council; the National Sciences and Engineering Research Council.

International Genetically Engineered Machines Competition (iGEM)

The premiere student team competition in Synthetic Biology, iGEM encourages students to work together to solve real-world challenges with genetically engineered biological systems. The 2017 iGEM Jamboree welcomed 3,000 synthetic biologists from around the globe with 310 student-led teams from 44 countries in attendance—this year there were 15 Canadian teams, and even more former Canadian participants working as judges and as part of the Safety Committee.

Through iGEM, we are able to monitor emerging technologies, influence responsible conduct of research, and network with knowledgeable experts and students on the broader implications of emerging technologies. We also instill good biosafety and risk-management practices, strengthen risk assessment methodologies for emerging technologies, and broaden our outreach to Canadian high school and undergraduate researchers, start-ups, and the DIY community.

STAKEHOLDER INITIATIVES

As experts in biosafety and biosecurity, we offer workshops and presentations on various biosafety and biosecurity topics. In 2017–2018, our participation at initiatives organized by our stakeholders highlights our role in promoting the adoption of a strong biosafety culture across Canada. These events provide significant engagement opportunities with Canadian biosafety professionals and scientific and academic communities.

The Canadian Biosafety Symposium

Hosted by the Canadian Association for Biological Safety, this annual symposium for biosafety representatives and professionals across Canada brings together participants working across the biosafety field in universities, government, and private sectors.

At the Symposium, **we delivered two presentations**—one about the first year of laboratory incident reporting, and one about the first year under the HPTA. We **co-hosted a Biosafety Café** with the Canadian Food Inspection Agency, inviting participants to discuss regulatory and biosafety topics, and ask questions. We also **delivered two additional post-symposium workshops**:

LABORATORY INCIDENT INVESTIGATION AND REPORTS	LOCAL RISK ASSESSMENTS
This workshop helped participants understand reporting obligations under the HPTA and HPTR and gain hands-on experience in laboratory incident investigation.	This workshop presented the different types of biosafety risk assessments and discussed the steps to conduct a local risk assessment and develop safe work practices.

Safeguarding Science

Led by Public Safety Canada, in collaboration with the Public Health Agency of Canada, the Canadian Nuclear Safety Commission, and other government partners, this outreach initiative supports Canada's counter proliferation efforts. Safeguarding Science aims to raise awareness within the scientific and academic communities of the risks of chemical, biological, radiological, and nuclear proliferation, as well as the potential for proliferation of dual-use technology.

From a biosecurity perspective, this targeted outreach and education initiative links science and security to reduce the risk of inadvertent or deliberate misuse of human pathogens and biological toxins in Canada's scientific research and developmental sectors, including academia and industry.

In support of this initiative, we provided subject matter expertise in biosecurity, participated in the delivery of 7 workshops, and facilitated a group discussion on biosecurity plan elements such as physical security, information security, and personnel suitability and reliability programs.

ADVANCING GLOBAL BIOSAFETY AND BIOSECURITY

Because an infectious disease threat anywhere can quickly become an infectious disease threat everywhere, we work globally to build international capacity in biosafety and biosecurity and pursue regulatory alignment in an effort to achieve strong international governance and oversight of biosafety and biosecurity. Through active leadership, partnerships, and global knowledge sharing on the safe use and secure containment of pathogens and toxins, we are helping to make Canada—and the world—a safer place.

We contribute our expertise to the health security goals and commitments of the Government of Canada. We provide leadership to develop sustainable global capacity in biosafety and biosecurity and our international work aligns with our domestic objectives.

GLOBAL PARTNERS

Our global biosafety and biosecurity efforts and engagements are guided by key international commitments and our World Health Organization (WHO) Collaborating Centre work plan. Additionally, in keeping with Canada's commitments as a member state of the G7 and G20, the Biosecurity Program supports the implementation of the International Health Regulations (IHR) core competencies through the Global Health Security Agenda (GHSA) and the Global Partnership against the Spread of Weapons and Materials of Mass Destruction.

Aligned with our domestic objectives and global health security efforts, we support national and regional health organizations around the world develop or strengthen their oversight frameworks.

World Health Organization Collaboration Centre

To strengthen global health security, with respect to biosafety and biosecurity, we have strategically aligned our work with the World Health Organization as a WHO Collaborating Centre for Biosafety and Biosecurity. Through this designation, we actively work to influence safe and secure practices for human pathogens and toxins in laboratories around the world. In return, the WHO and its members benefit from Canadian expertise and experience to improve biosafety guidelines, compliance monitoring, and verification activities. For example, in 2017–2018, we shared laboratory exposure reporting data and best practices with the WHO to support the evidence basis for biosafety advice, build systems capacity, and promote biosafety incident reporting in other countries.

Global Partnership against the Spread of Weapons and Materials of Mass Destruction

To deliver on our international commitments, we leverage funding from Global Affairs Canada (GAC) through the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction. The objective is to prevent terrorists, or those harbouring them, to acquire or develop nuclear, chemical, radiological, and biological weapons. The Biosecurity Program also provides GAC with subject matter expertise and support upon request.

Global Health Security Agenda (GHSA)

Launched in February 2014, the GHSA is a growing partnership of over 64 nations, international organizations, and non-governmental stakeholders. The GHSA aims to help build the capacity of countries to advance a world that is safer and more secure from infectious disease threats. It also elevates global health security as a national and global priority.

Our global health security efforts are strategically aligned with the GHSA, and we have positioned ourselves as a lead country to the Prevent 3 Action Package on biosafety and biosecurity.

GLOBAL CAPACITY BUILDING

Building sustainable biosafety and biosecurity capacity at national and regional levels contributes to an increase in global capacity overall and reduces the risk of an incident in another country or region that could have significant implications for Canada.

Analytical Approach

In support of Canadian commitments under the Global Health Security Agenda and the G7 to building International Health Regulations (IHR) core competencies; we developed an Analytical Approach that can be used by national, regional, and local authorities to devise national biosafety and biosecurity oversight frameworks.

The Analytical Approach is a modular, scalable policy toolkit designed to assist countries or regions to develop, refine, or evaluate a policy oversight framework for biosafety and biosecurity. In 2017–2018, we finalized the first edition.

The **Analytical Approach** also complements the Government of Canada's global health security efforts, including building IHR core competencies, the G7 commitments, the G20, the Global Partnership Plan (GPP), the Global Health Security Initiative (GHSI) and regional forums (e.g. Caribbean Public Health Agency).

To deliver a finalized Analytical Approach that could be used successfully by a wide variety of countries and regions, we conducted pilot workshops with Mali (January 2017), Trinidad and Tobago, Laos (December 2017), and Sierra Leone (February 2018)—many other countries have already expressed an interest in applying the tool to develop their own national frameworks. The development of the Analytical Approach and piloting the tool was funded by Global Affairs Canada through the Global Partnership Program.

INTERNATIONAL REGULATORY INFLUENCE

As global leaders and influencers in biosafety and biosecurity, we are well positioned to encourage alignment among national regulators and share lessons learned through fora such as the International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR) and the European Enforcement Project (EEP), as well as through WHO initiatives and contributions as a designated WHO Collaborating Centre.

Strong International Regulatory Oversight

Established by the Program in 2007 to strengthen and advance biosafety and biosecurity regulatory oversight mechanisms internationally, the IEGBBR consists of government biosafety and biosecurity regulatory officials from around the world.

As co-chairs of the forum, we provided secretariat support from September 2016 to December 2017 with funding support from GAC. Continuing this role, in 2017–2018, we successfully secured funding through GAC for the secretariat function through to January 2018 and hosted the 9th meeting of the IEGBBR.

Global Knowledge Exchange

As a member of the EEP on Genetically Modified Organisms (GMO), we are part of a network of regulators from inspectorates across the European Union (EU) and other EEP member states. The goal of the EEP is to exchange knowledge and experiences related to legislated compliance activities to address shared challenges and promote the harmonization of enforcement practices and strategies across the EU and beyond.

As the only non-European member, involvement in this network and participation at the EEP annual meeting provides us with a unique opportunity to share lessons learned, international best practices, and tools with other national pathogen inspection programs.

In 2017–2018, we delivered a presentation at the EEP on our experience with occupational health and safety considerations for laboratory inspectors.

Global Initiatives

As part of WHO's Global Polio Eradication Initiative, Canada's National Authority for Containment (NAC) was established within the Program in 2015. As the NAC, we are responsible for implementing global polio containment requirements in Canada, which includes auditing designated facilities that are planning to retain poliovirus in the post-eradication era to minimize the risk of reintroduction.

Reducing the number of poliovirus containment facilities around the world minimizes the risk of the disease re-emerging. Through targeted outreach and engagement with our regulated parties, the number of Canadian labs working with poliovirus has gone from 23 in 2009 to 6 in 2017–2018.

In 2017–2018, as part of our commitment to the Polio Eradication & Endgame Strategic Plan (2013–2018) and implementing the WHO's Global Action Plan (GAPIII) via the GAPIII Containment Certification Scheme:

- Two of our inspectors successfully completed the WHO's intensive Training for Auditors and received their designation as Polio Lead Auditors.
- Canada's Annual National Report was formally submitted to the Pan American Health Organization to continue meeting our contribution to Phase I.

Technical Expertise and Support

As part of our ongoing membership on the WHO Laboratory Biosafety Manual LBM Editorial team, we made significant and ongoing contributions to the revision of the WHO Laboratory Biosafety Manual and continued leading the development of a select number of sections based on our expertise in risk assessment and regulatory activities (e.g., Biosafety Program Management monograph).

In 2017–2018, as a designated WHO Collaborating Centre for Biosafety and Biosecurity, we provided technical expertise and support for the following WHO global activities:

- Smallpox inspections, resulting in a renewed process, strengthened transparency, and enhanced capacity within WHO to conduct inspections.
- Construction of laboratory infrastructure in Côte d'Ivoire.
- Creation of and feedback on the first iteration of the ISO Biorisk Management Standard (ISO 35001), allowing consideration of the Canadian context in the development of international standards.

These highlights of our global biosafety and biosecurity security efforts demonstrate how we are working globally to strengthen data collection and analysis, build policy tools, and establish networks of trusted experts and regulators. Strong, united global regulatory efforts—large and small—help keep our country and international communities safe from pathogens and toxin related risks to public health and safety.